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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER
NAJARIAN, LENA

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MAILED

Application Number: 09/534,946
Filing Date: March 24, 2000
Appellant(s): RUDERMAN ET AL.

AUG 0 8 2007

GROUP 3600

John J. McDonnell
<u>For Appellant</u>

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/11/07 appealing from the Office

action mailed 5/31/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,724,580	LEVIN	3-1998
6,576,471	OTVOS	6-2003
5,925,229	KRAUSS	7-1999

6,024,699   SURWIT   2-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22, 24-28, and 38 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Levin et al. (5,724,580) in view of Otvos (6,576,471), Krauss et al.

(5,925,229), and Applicant's Background of the Art (page 1 of specification).

(A) As per claim 38, Levin discloses a system for managing coronary disease data

(reads on "managing cardiovascular healthcare information") (col. 1 lines 9-18, col. 2

lines 39-45 and 50-57, and col. 11 lines 12-15) comprising:

(a) a centralized data management center for maintaining a record of data

received by and transmitted from relational databases relating to coronary disease data,

wherein the records include patient diagnosis and treatment information collected over

time, wherein the processing means at the centralized data management center provide

for analyzing patient test results using a coronary wellness master algorithm and

artificial intelligence, such as analyzing ECG information, lipid data, including total

cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (Fig.

3 and 25A, col. 5 lines 1-36, col. 6 lines 3-28, col. 7 lines 55-63, col. 7 line 64 to col. 8

line 7, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and

col. 12 line 46 to col. 14 line 10), wherein the processing means runs a lipid

classification algorithm by inputting patient's LDL and HDL cholesterol values and

checking the patient values against the upper limit for normal LDL and HDL cholesterol

values, wherein the normal values are stored in the databases at the centralized data

management center (Fig. 1-2, 4, and 11-15, Abstract lines 11-14, col. 5 lines 25-37, col.

8 line 21 to col. 9 line 40, col. 10 lines 56-57, and col. 11 lines 5-10);

(b) a monitor displaying a menu (reads on "data entry interface") for entering all

known and required information, including patient information such as name, birth date,

sex, height, and weight, and test results, such as lipid data, including total cholesterol,

LDL cholesterol, and HDL cholesterol, and storing the information and test results at the

centralized data management center databases (Abstract lines 11-14, Fig. 1-2, col. 4

line 53 to col. 5 line 36, col. 10 lines 50-57, and col. 11 lines 5-10); and

(c) processing means at the centralized data management center for analyzing

patient test results using a coronary wellness master algorithm and artificial intelligence,

such as ECG information, lipid data, including total cholesterol, LDL cholesterol, and

HDL cholesterol, and blood pressure of a patient (reads on "diagnostic engine") (col. 7

lines 55-63, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-

55, and col. 12 line 46 to col. 14 line 10), wherein the algorithm correlates test results

with risk factors for coronary artery disease and possible treatment recommendations

with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy,

antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig.

25A-B and col. 10 lines 3-15), wherein an example of the correlation of risk factors

includes running a classification of a patient into either an HDL cholesterol acceptable

class or a HDL cholesterol low class or HDL elevated class (Fig. 25A-B and col. 8 lines

20-60).

In addition, Levin includes within Figures 11-15 measuring HDL and LDL levels

using the units of mg/DL and then classifying the patient into an appropriate class,

either an elevated class or optimal class based on the HDL and LDL levels (col. 8 lines

21-47). It is noted that HDL and LDL levels are sub classes of a patient's total

cholesterol (Fig. 11-15 and col. 8 lines 21-47).

Levin does not expressly disclose the database storing data of at least 900

patients. However, Levin clearly teaches that the pool of patient information stored in

the database will grow over time (col. 6 lines 3-15). The Examiner respectfully submits

that it is well known in the medical database arts to store data for large numbers of

patients. For example, it is well known that large hospitals and even small medical

practices have databases storing records for more than 900 patients. It would have

been obvious at the time of Applicant's invention to include this feature with the

motivation of determining the effectiveness of diagnoses and treatments as information

is gathered over time based on large numbers of patients (Levin; col. 6 lines 3-15).

Levin fails to expressly disclose test results of concentration of subclasses of

LDL and subclasses of HDL from cardiovascular patients.

Otvos discloses generating lipoprotein measurement values for a patient's blood

sample, the lipoprotein measurement values including a plurality of lipoprotein subclass

variable measurements, including LDL size, LDL concentration (reads on "concentration

of subclasses of LDL"), large HDL concentration (reads on "concentration of subclasses

of HDL"), large VLDL concentration, LDL-C, and HDL-C (see Fig. 2: 71), comparing the

plurality of patient lipoprotein subclass variable values with respective predetermined

test criteria for determining whether the subclass variable values are associated with a

higher or lower risk of developing coronary heart disease, evaluating the lipoprotein

measurement values and generating a reduced target value or values for what

represents an optimal or low risk value for selected lipoprotein constituents to provide a

patient-specific treatment guideline based on the presence of predetermined risk

criteria, and automatically generating personalized lipoprotein-based reports for patients

(Fig. 1: 32, 32a, 33, 33a, 33b, 43, 43a, 43b, Fig. 2, 2A, 3, 4, 5, 7, 8, 9, 11, 14, col. 3 line

32 to col. 4 line 5, col. 5 lines 22-45, col. 11 lines 12-46, col. 16 lines 48-62, col. 19 line

55 to col. 20 line 40).

At the time the invention was made, it would have been obvious to one of

ordinary skill in the art to include the aforementioned lipoprotein subclass variable

measurements of Otvos within the system taught by Levin with the motivation of

accurately diagnosing a patient with coronary artery disease by using a comprehensive

set of data thus allowing a physician to effectively manage coronary artery disease

(Levin; col. 2 lines 15-60) and utilizing subclass information for lipoproteins because

subclass information provides a more reliable indicator of a patient's risk to develop coronary heart disease (Otvos; col. 1 lines 55-65).

As per the recitation of "identifying patients who do not have hyperlipidemia but are in need of treatment", Otvos teaches using NMR spectroscopy to obtain subclass information, wherein the subclass information is a more reliable indicator of a patient's risk to develop coronary heart disease, wherein various subclasses of lipoproteins may provide more reliable markers of the metabolic conditions that predispose individuals to a greater or lesser risk of heart disease (col. 1 line 42 to col. 2 line 11). Further, Otvos teaches that without an NMR subclass profile, a patient with a specific type of lipid profile may have been overlooked as a candidate for further review or potential behavior altering counseling (or even drug therapy) because of the number of borderline lipid measurement results (col. 16 lines 48-62). It is respectfully submitted that using an NMR subclass profile, such as that disclosed by Otvos, is a means for identifying patients who do not have hyperlipidemia but are in need of treatment (i.e., patients who would ordinarily be overlooked). The motivation being to improve the health care of patients by using the subclass information as a more reliable indicator of a patient's risk to develop coronary heart disease (col. 1 line 42 to col. 2 line 11).

Levin and Otvos fail to expressly disclose the subclasses of LDL particles and subclasses of HDL particles being levels determined by segmented gradient gel electrophoresis.

Krauss discloses using segmented gradient gel electrophoresis to determine the subclasses of LDL particles and HDL particles (col. 1 line 15 to col. 2 line 47, col. 14 line 61 to col. 16 line 22)

At the time the invention was made, it would have been have been obvious to one of ordinary skill in the art to combine the features of Krauss within the system of Levin and Otvos with the motivation of providing a rapid and inexpensive assay for quantifying LDL and HDL subclasses (Krauss; col. 2 lines 49-67).

As per the recitation of "the particle subclasses including HDL2b," it is respectfully submitted that the Applicant's Background of the Invention discloses that "the art describes cardiovascular risk factors such as... lipid profiles including LDL and HDL and subclasses (fractions) of LDL and HDL. Methods for measuring these factors and relating them to patient treatment are also known." The Examiner respectfully submits that it is well known in the art that HDL2b is a major subclass of high-density lipoproteins. It would appear from Applicant's Background of the Invention that this would be a "cardiovascular risk factor" that is well known in the art. The motivation for measuring this factor using segmented gradient gel electrophoresis being to provide an ever more nuanced picture of the cardiovascular disease process that will enable doctors to better assess which patients are at risk for heart disease, stop heart attacks before they happen and develop more effective, customized treatment plans.

(B) As per claim 22, Levin discloses a monitor displaying a menu (reads on "physician data access interface") for providing a physician, such as a cardiologist, with the ability

to access, display, review, and transfer information stored at the centralized data

management center (col. 2 lines 1-15, col. 5 lines 49-67, and col. 11 lines 1-10).

(C) As per claim 24, Levin discloses a storage means that stores information related to

coronary illness risk factors which have been established based on empirical data,

wherein the information allows physicians to determine the effectiveness of diagnoses

and treatments as the information is gathered over time and as the pool of treated

patients increases (Abstract lines 11-14, col. 6 line 3-15, and col. 10 lines 3-15). It is

respectfully submitted that the storage means disclosed by Levin is a form of a

knowledge base as the data collected in the database is a collection of knowledge of

specialists such as cardiologists, and the data collected will be used to effectively

identify patients at significant risk of sudden death and to quantify the success of

various treatments both for the patient pool and for particular patients (col. 6 line 3-15).

(D) As per claims 25-27, Levin discloses processing means at the centralized data

management center for analyzing patient test results using a coronary wellness master

algorithm and artificial intelligence, wherein patient test results include ECG information,

lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood

pressure of a patient, and wherein the test results determine base numbers for a patient

(reads on "diagnostic engine" and "baseline determination for ongoing therapy

monitoring") (Fig. 3, col. 5 lines 25-36, col. 6 lines 16-28, col. 7 lines 55-63, col. 7 line 64

to col. 8 line 7, col. 8 line 21 to col. 39, col. 9 lines 18-39, col. 10 lines 3-15, col. 10 lines

3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10) wherein:

(a) the algorithms correlate test results with possible treatment recommendations

with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy,

antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig.

25A-B and col. 10 lines 3-15);

(b) the algorithms correlate test results with possible or recommended

diagnoses, such as such as whether the levels of total cholesterol, LDL cholesterol, and

HDL cholesterol are acceptable or not, and the diagnosis classification for blood

pressure of a patient, wherein the classification includes normal, high-normal, mild

hypertension, moderate hypertension, severe hypertension, and very severe

hypertension (col. 8 line 21 to col. 9 line 39, col. 10 lines 3-15, and col. 11 line 10-15);

and

(c) the algorithms correlate diagnosis information with possible or recommended

treatments (Fig. 25A-B, col. 5 lines 16-37, col. 6 line 16 to col. 7 line 47, col. 8 line 21 to

col. 9 line 39, and col. 10 lines 3-15).

(E) As per claim 28, Levin discloses the algorithms correlating test results with possible

treatment recommendations with regard to antischemic therapy, hypolipidemic therapy,

antihypertensive therapy, antithrombotic therapy (reads on "personalized drugs"),

diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-

15).

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580), Otvos (6,576,471), Krauss et al. (5,925,229), and Applicant's Background of the Art (page 1 of specification), and further in view of Surwit et al. (6,024,699).

(A) As per claim 23, the relevant teachings of Levin and Otvos, and the motivation for their combination is as discussed in the rejections above, and incorporated herein.

Levin, Otvos, and Krauss fail to expressly disclose a communication system allowing the physician to communicate cardiovascular healthcare management information to a patient. However, Levin includes communicating coronary illness information to and from a physician, such as a cardiologist, via communication network (Fig. 1-3 and 25A-25B, col. 2 line 62 to col. 3 line 10, col. 4 lines 31-55, col. 7 lines 33-47, and col. 7 line 64 to col. 8 line 7).

Surwit discloses a system for monitoring, diagnosing, prioritizing, and treating chronic medical conditions of a plurality of remotely located patients, wherein treatment information is provided to a patient via a computer network (Fig. 1 and 3, col. 2 lines 38-55, col. 3 lines 24-38, col. 6 line 27 to col. 7 line 13, col. 9 lines 24-58, col. 18 line 45 to col. 19 line 40).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned component of Surwit within the system taught collectively by Levin, Otvos, and Krauss with the motivation of quickly and easily monitoring patients and automatically identifying a patient with a medical

condition, quickly preparing and revising medicine dosages for a patient and then

efficiently communicating revised dosage information to a patient (Surwit; col. 2 lines

25-35), and reducing the costs of medical treatment by providing a fast, effective

technique for providing comprehensive management of coronary patients based on risk

factors including up to date diagnoses and treatment information (Levin; col. 2 lines 16-

49).

(10) Response to Argument

In the Appeal Brief filed 11 April 2007, Appellant makes the following arguments:

A) Levin does not recognize the LDL subclass and HDL subclass analysis can

identify patients that have apparently normal LDL and HDL total values. If anything

Levin teaches away from applicant's invention in that it only considers total HDL and

LDL in the data base.

B) Otvos does not recognize the possibility of identifying patients with normal

LDL and HDL who need treatment and the NMR technique is incapable of doing so.

C) Krauss only describes the use of segmented gel electrophoresis to determine

some LDL subclasses and does not describe the separation of HDL subclass. Krauss

does not describe a database of LDL subclasses or HDL subsclasses. Krauss does not

describe any HDL subclasses, much less the HDL2b subclass present in the data base

of the claimed health care management system.

D) To properly combine references to reach a conclusion of obviousness, there

must be some teaching, suggestion or inference in the references, or knowledge

generally available to one of ordinary skill in the art, which would have led one to

combine the relevant teaching of the two references. There is no suggestion to

combine Levine, Otvos and Krauss to provide a healthcare management system for

identifying patients who do not have hyperlipidemia based on total LDL cholesterol and

total HDL cholesterol, but are in need of treatment.

Examiner will address Appellant's arguments in sequence as they appear in the

brief.

Arguments A, B, and C:

In response to Appellant's first three arguments, the Examiner respectfully

submits that Levin was relied upon for teaching the basic architecture of the system

claimed by Appellant. The Examiner provided Otvos to teach subclasses of HDL and

LDL. Appellant argues that Krauss fails to teach HDL 2b. The Examiner did not rely

upon Krauss for this feature. The Examiner pointed out that Applicant's Background of

the Invention teaches or suggests this feature.

Argument D:

In response to applicant's argument that there is no suggestion to combine the

references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner has provided motivations to combine the applied prior art directly from the references themselves. Note the motivation provided for combining Otvos within Levin of accurately diagnosing a patient with coronary artery disease by using a comprehensive set of data thus allowing a physician to effectively manage coronary artery disease (Levin; col. 2 lines 15-60) and utilizing subclass information for lipoproteins because subclass information provides a more reliable indicator of a patient's risk to develop coronary heart disease (Otvos; col. 1 lines 55-65). As such, it is respectfully submitted that an explanation based on logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention that supports a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner.

In addition, the Examiner respectfully submits that *KSR* forecloses Appellant's argument that a specific teaching is required for a finding of obviousness. *KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Lena Najarian

Lena Najarian

LN

July 30, 2007

Conferees:

C. Luke Gilligan
Primary Examiner
Tech Center 3600

Vincent Millin
Appeals Conference Specialist
Tech Center 3600

JOHN J. McDONNELL
McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606

C. LUKE GILLIGAN
PRIMARY EXAMINER
TECHNOLOGY CENTER 3600